NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IMPAX LABORATORIES, INC.,	:	
Plaintiff,	:	Civil Action No. 15-6934 (SRC) (consolidated)
v.	:	
	:	**OPINION & ORDER**
ACTAVIS LABORATORIES FL, INC. et al.,	:	
Defendants.	:	

CHESLER, U.S.D.J.

This matter comes before this Court on the motion for summary judgment, pursuant to Federal Rule of Civil Procedure 56, by Defendants Actavis Laboratories FL, Inc. and Actavis Pharma Inc. (collectively, "Actavis"). Plaintiff Impax Laboratories, Inc. ("Impax") has opposed the motion. The Court heard oral argument on this motion on February 27, 2018. For the reasons stated below, the motion will be granted in part and denied in part.

BACKGROUND

This is a Hatch-Waxman case involving a patent dispute regarding pharmaceuticals: the Complaint alleges that Actavis seeks to make and sell a generic version of Plaintiff's Rytary® (levodopa/carbidopa) capsules prior to the expiration of the relevant patents. This consolidated case now involves four patents. Actavis moves for summary judgment that its proposed generic product will not infringe 37 claims in U.S. Patent Nos. 8,557,283 ("the '283 patent"), 9,089,608

("the '608 patent"), 9,463,246 ("the '246 patent"), and 9,533,046 ("the '046 patent"):[1]

Patent	Claims
'283	1, 2, 3, 5
'608	5, 8, 10, 13, 17, 18, 19
'246	1, 9, 14, 17, 19, 21, 25, 26, 37, 40, 42, 44, 48, 49, 51, 53
'046	7, 12, 14, 16, 18, 20, 21, 30, 31

The patents cover pharmaceutical formulations and methods of use.

APPLICABLE LEGAL STANDARDS

I. Motion for summary judgment

Summary judgment is appropriate under FED. R. CIV. P. 56(c) when the moving party demonstrates that there is no genuine issue of material fact and the evidence establishes the moving party's entitlement to judgment as a matter of law. Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986). A factual dispute is genuine if a reasonable jury could return a verdict for the non-movant, and it is material if, under the substantive law, it would affect the outcome of the suit. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). "In considering a motion for summary judgment, a district court may not make credibility determinations or engage in any weighing of the evidence; instead, the non-moving party's evidence 'is to be believed and all justifiable inferences are to be drawn in his favor.'" Marino v. Indus. Crating Co., 358 F.3d 241, 247 (3d Cir. 2004) (quoting Anderson, 477 U.S. at 255).

"When the moving party has the burden of proof at trial, that party must show affirmatively the absence of a genuine issue of material fact: it must show that, on all the

[1] Actavis moved for summary judgment of noninfringement on a set of claims which included claim 21 of the '608 patent. In response, Impax stated that it is no longer asserting this claim in this case. (Impax Opp. Br. 7 n.3.) Because Impax has abandoned its claim of infringement of claim 21 of the '608 patent, as to this claim, the motion for summary judgment of noninfringement will be granted.

essential elements of its case on which it bears the burden of proof at trial, no reasonable jury could find for the non-moving party." In re Bressman, 327 F.3d 229, 238 (3d Cir. 2003) (quoting United States v. Four Parcels of Real Property, 941 F.2d 1428, 1438 (11th Cir. 1991)). "[W]ith respect to an issue on which the nonmoving party bears the burden of proof . . . the burden on the moving party may be discharged by 'showing' – that is, pointing out to the district court – that there is an absence of evidence to support the nonmoving party's case." Celotex, 477 U.S. at 325.

Once the moving party has satisfied its initial burden, the party opposing the motion must establish that a genuine issue as to a material fact exists. Jersey Cent. Power & Light Co. v. Lacey Township, 772 F.2d 1103, 1109 (3d Cir. 1985). The party opposing the motion for summary judgment cannot rest on mere allegations and instead must present actual evidence that creates a genuine issue as to a material fact for trial. Anderson, 477 U.S. at 248; Siegel Transfer, Inc. v. Carrier Express, Inc., 54 F.3d 1125, 1130-31 (3d Cir. 1995). "[U]nsupported allegations . . . and pleadings are insufficient to repel summary judgment." Schoch v. First Fid. Bancorporation, 912 F.2d 654, 657 (3d Cir. 1990); see also FED. R. CIV. P. 56(e) (requiring nonmoving party to "set out specific facts showing a genuine issue for trial"). "A nonmoving party has created a genuine issue of material fact if it has provided sufficient evidence to allow a jury to find in its favor at trial." Gleason v. Norwest Mortg., Inc., 243 F.3d 130, 138 (3d Cir. 2001).

If the nonmoving party has failed "to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial, . . . there can be 'no genuine issue of material fact,' since a complete failure of proof

concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial." Katz v. Aetna Cas. & Sur. Co., 972 F.2d 53, 55 (3d Cir. 1992) (quoting Celotex, 477 U.S. at 322-23).

II. Patent infringement and claim construction

A court's determination "of patent infringement requires a two-step process: first, the court determines the meaning of the disputed claim terms, then the accused device is compared to the claims as construed to determine infringement." Acumed LLC v. Stryker Corp., 483 F.3d 800, 804 (Fed. Cir. 2007). "[W]hen the district court reviews only evidence intrinsic to the patent (the patent claims and specifications, along with the patent's prosecution history), the judge's determination will amount solely to a determination of law." Teva Pharms. USA, Inc. v. Sandoz, Inc., 135 S. Ct. 831, 841 (2015).

The focus of claim construction is the claim language itself:

> It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude. Attending this principle, a claim construction analysis must begin and remain centered on the claim language itself, for that is the language the patentee has chosen to 'particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention.'

Innova/Pure Water, Inc. v. Safari Water Filtration Sys., 381 F.3d 1111, 1115-1116 (Fed. Cir. 2004) (citations omitted).

The Federal Circuit has established this framework for the construction of claim language:

> We have frequently stated that the words of a claim 'are generally given their ordinary and customary meaning.' We have made clear, moreover, that the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.

> The inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation. . .
>
> In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words. In such circumstances, general purpose dictionaries may be helpful. In many cases that give rise to litigation, however, determining the ordinary and customary meaning of the claim requires examination of terms that have a particular meaning in a field of art. Because the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, and because patentees frequently use terms idiosyncratically, the court looks to those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean. Those sources include the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.

Phillips v. AWH Corp., 415 F.3d 1303, 1312-1314 (Fed. Cir. 2005) (citations omitted).

DISCUSSION

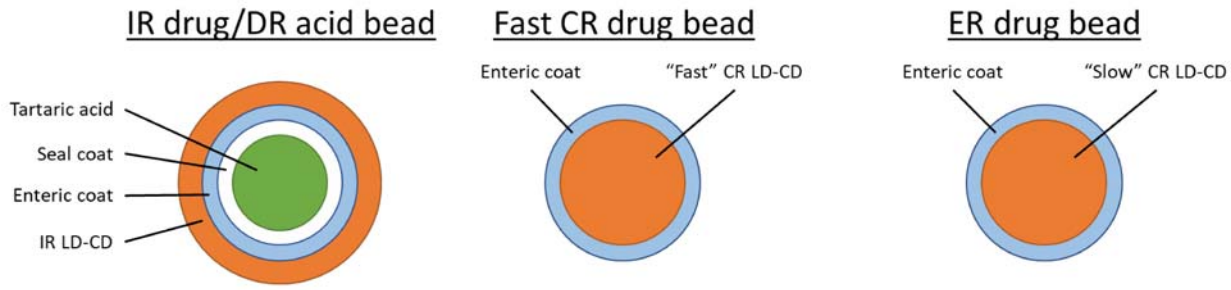
All of the claims at issue from the ’283, ’246 and ’046 patents are directed to methods of use. All of the claims at issue from the ’608 patent are directed to formulations. The parties do not dispute that, therefore, Actavis cannot be liable for direct infringement of claims directed to methods of use, because it will not use its product to treat patients, but will sell the product for others to use. Actavis can only be liable for indirect infringement of any method claims.

The parties have divided the claims into two groups, for purposes of this motion, based on a different distinction: whether the infringement dispute for a particular claim turns on an issue of formulation structure (whether the carboxylic acid component is in a distinct bead) or an issue of pharmacokinetic (“PK”) profile (whether the method results in a levadopa plasma concentration profile with certain characteristics).

I. Infringement of claims requiring a particular formulation structure

For purposes of this motion, the parties have grouped together claims in the ’283 and ’608 patents that contain this phrase: “(a) levodopa; (b) a decarboxylase inhibitor; and (c) a carboxylic acid that is not (a) or (b); wherein the carboxylic acid of (c) is in a distinct bead from (a) or (b).” Thus, claims 1, 2, 3, and 5 of the ’283 patent, and claims 5, 8, 10, 13, 17, 18, and 19 of the ’608 patent form a subset that will be referred to as the “Formulation Structure Claims.” Actavis moves for summary judgment of literal noninfringement on all such claims on the ground that its proposed product does not meet this limitation. While Actavis makes a number of arguments, the heart of its noninfringement case for these claims is the contention that its proposed product does not meet this limitation, and thus cannot literally infringe.[2]

The parties do not dispute that the proposed Actavis product has this formulation structure:



Actavis contends that, as this diagram demonstrates, the bead with tartaric acid, a carboxylic

[2] Both sides also devote many pages to arguments about how this Court’s claim construction of the phrase “distinct component” in the ’474 patent applies (or does not apply) here. Federal Circuit law is clear: “the prosecution of one claim term in a parent application will generally not limit different claim language in a continuation application.” Invitrogen Corp. v. Clontech Labs., Inc., 429 F.3d 1052, 1078 (Fed. Cir. 2005). “Distinct bead” is different claim language from “distinct component.” This Court’s claim construction of one phrase does not provide a shortcut in an inquiry into the meaning of a different phrase.

acid, also contains levodopa ("LD") and a decarboxylase inhibitor ("CD.") As a result, the proposed product does not contain the claim limitation at issue: the carboxylic acid is not in a distinct bead from the levodopa and decarboxylase inhibitor.

In opposition, Impax does not dispute any of the pertinent facts. Instead, it argues, in effect, that the words "the carboxylic acid is in a distinct bead from (a) or (b)" do not have their plain meaning: "Nor does the claim say the carboxylic acid acid must be in a bead 'with no CD/LD' as Actavis would prefer."[3] (Impax Opp. Br. 13.) This is a "sky is green" argument. The phrase, "the carboxylic acid is in a distinct bead from (a) or (b)," plainly requires that the carboxylic acid must be in a bead with no carbidopa or decarboxylase inhibitor. Impax has no basis – none – for its interpretation to the contrary. Impax has offered no basis for this Court to understand this phrase in a way that is contrary to its plain meaning.

Actavis moved for summary judgment of noninfringement as to literal infringement of the claims requiring a "distinct bead" structure. Impax, the patentee, bears the burden of proof of infringement at trial:

> The *Celotex* Court also made clear that all that is required is "notice [to the party with the burden of proof] that she had to come forward with all of her evidence." In the light of *Celotex*, we conclude that nothing more is required than the filing of a summary judgment motion stating that the patentee had no evidence of infringement and pointing to the specific ways in which accused systems did not meet the claim limitations.

Exigent Tech. v. Atrana Sols., Inc., 442 F.3d 1301, 1308-09 (Fed. Cir. 2006) (citation omitted). Actavis satisfied its initial summary judgment burden under Federal Circuit law, and the burden

[3] Impax proposes a radical reinterpretation of the "distinct bead" limitation, one which requires only that there be some carbidopa and levodopa in separate beads from the carboxylic acid bead. (Impax Opp. Br. 14.) Based on the present record, the claim language at issue cannot support this.

then shifts to Impax to point to sufficient evidence for a jury to return a verdict in its favor. Armbruster v. Unisys Corp., 32 F.3d 768, 777 (3d Cir. 1994).

Impax makes a number of additional arguments. Actavis had argued that this Court should apply the prosecution disclaimer it had found during claim construction of the '474 patent to the claims at issue in the '283 and '608 patents. Impax argues against doing so, citing Regents of the Univ. of Minn. v. AGA Med. Corp., 717 F.3d 929, 943-44 (Fed. Cir. 2013) (citations omitted), which held:

> We have explained that "[w]hen the purported disclaimers [made during prosecution] are directed to specific claim terms that have been omitted or materially altered in subsequent applications (rather than to the invention itself), those disclaimers do not apply." In general, a prosecution disclaimer will only apply to a subsequent patent if that patent contains the same claim limitation as its predecessor.
>
> Thus, our cases establish that the two patents must have the same or closely related claim limitation language. If the language of the later limitation is significantly different, the disclaimer will not apply. . .
>
> The proper inquiry is whether the scope of the claim limitation is substantially the same in the subsequent application as it was in the earlier application. . . . This is why our cases evaluate the similarity between the earlier and later claim limitations, carrying disclaimer forward if there are only immaterial differences.

This Court need not consider in detail the question of whether the disclaimer found in the prosecution history of the '474 patent should be applied to the '283 and '608 patents, which descended by way of continuation application from the application that led to the '474 patent. At short, at issue in this Court's claim construction for the '474 patent was the claim term "distinct component," while the claim term "distinct bead" is presently at issue. Actavis, in its opening brief, neither raised nor addressed the issue of the difference between the claim term, "distinct component," in the context of the '474 patent, and "distinct bead," in the context of the

’283 and ’608 patents. Thus, in the present briefing, Actavis has failed to lay the foundation that would be necessary for this Court to conclude, as a matter of claim construction, that the ’474 prosecution disclaimer regarding “distinct component” should apply to “distinct bead” in the ’283 and ’608 patents. This Court concludes that, on this record, Actavis has failed to persuade that the ’474 prosecution disclaimer should apply to “distinct bead” in the ’283 and ’608 patents.

The present dispute between the parties over literal infringement of the formulation structure claims turns on a claim construction dispute over “the carboxylic acid is in a distinct bead from (a) or (b).” In short, Actavis contends that this means what it says, while Impax contends that, for unclear reasons, this means the opposite of what it says. On this record, this Court finds no support for Impax’ position. There is simply no way to understand this phrase except to require that the carboxylic acid be on a bead that contains no levodopa and also contains no decarboxylase inhibitor. As shown in the diagram above, it is undisputed, as a factual matter, that the Actavis proposed product places the carboxylic acid, tartaric acid, on a bead that also has a layer containing levidopa and carbidopa, a decarboxylase inhibitor. As to the literal infringement claim for those ’283 and ’608 patent claims which include the limitation, “the carboxylic acid is in a distinct bead from (a) or (b)” (the Formulation Structure Claims), Impax has failed to point to any evidence that raises a material factual dispute. As such, Impax has failed to defeat Actavis’ motion as to these claims, and the motion for summary judgment of noninfringement will be granted, as to literal infringement of the Formulation Structure Claims.

As to infringement of the Formulation Structure Claims under the doctrine of equivalents, Actavis moves for summary judgment of noninfringement, on one ground: applying the doctrine of prosecution history estoppel, Impax is barred from using the doctrine of equivalents to

recapture claim scope that it surrendered during prosecution. See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 734 (2002). Actavis, in its moving brief, devotes two pages to this argument, giving cursory treatment to a complicated subject. Actavis argues, in short, that this Court found an effective disclaimer of claim scope in the prosecution history of the '474 patent, and then jumps to the assertion that Impax is therefore barred from recapturing any of that scope under a doctrine of equivalents theory with regard to patents in the same family (the Formulation Structure Claims).

This Court today makes no determination about the merits of this prosecution history estoppel argument. Actavis has given the Court a very few dots outlining the trail of a possible future argument, and this Court will not *sua sponte* fill in the missing sections to create a complete path. Actavis points to the Federal Circuit's decision in Elkay Mfg. Co. v. Ebco Mfg. Co., 192 F.3d 973, 980 (Fed. Cir. 1999): "When multiple patents derive from the same initial application, the prosecution history regarding a claim limitation in any patent that has issued applies with equal force to subsequently issued patents that contain the same claim limitation." There is no dispute that the '283, '608, and '474 patents derive from the same initial application. The challenge for Actavis, as to this argument, is the "same claim limitation" requirement. As already discussed, this Court found a disclaimer in the '474 prosecution history leading to claims with a "distinct component" limitation. The Formulation Structure Claims do not contain this phrase but, instead, the phrase, "distinct bead." There is a logical gap here that Actavis must bridge to persuade this Court that a prosecution disclaimer related to "distinct component" applies with equal force to patent claims with a different claim limitation.

Furthermore, as Impax argues, claims 1, 7, and 59 in the '474 patent are not duplicates of

the Formulation Structure Claims at issue now, but have salient differences: there are additional limitations, interwoven throughout the claims, relating to controlled release components and immediate release components. Compare the operative claim language. The Formulation Structure Claims share this limitation: "(a) levodopa; (b) a decarboxylase inhibitor; and (c) a carboxylic acid that is not (a) or (b); wherein the carboxylic acid of (c) is in a distinct bead from (a) or (b)." Claim 1 of the '474 patent contains this limitation:

> a. a controlled release component comprising levodopa, a decarboxylase inhibitor and one or more rate controlling excipients, b. a carboxylic acid component comprising a carboxylic acid that is not levodopa or the decarboxylase inhibitor and one or more rate controlling excipients, and c. an immediate release component comprising levodopa and a decarboxylase inhibitor, wherein the carboxylic acid component of (b) is a distinct component and is coated with an enteric polymer . . .

The Formulation Structure Claims do not contain language relating to rate of release. Thus, not only do the Formulation Structure Claims use different claim language ("distinct bead"), but this claim limitation appears on its face to raise different issues.[4] This Court today takes no position on whether a fuller treatment of the prosecution history estoppel argument might be successful. Based on the present record, however, Actavis has not persuaded the Court that prosecution history estoppel limits Impax's use of the doctrine of equivalents with regard to the Formulation Structure Claims. As to the issue of the use of prosecution history estoppel to limit Impax's use of the doctrine of equivalents with regard to the Formulation Structure Claims, the motion for summary judgment will be denied.

In opposition, Impax contends that, even if the Court interprets the claim language to

[4] It would be one thing if the (a), (b), and (c) in the '474 claim were identical to the (a), (b), and (c) in the '283 and '608 claims, but they are not identical, and Actavis has not addressed the impact of this difference.

require that the carboxylic acid be on a bead that does not contain levidopa and a decarboxylase inhibitor, the Actavis product is still equivalent. Impax contends that, 15 minutes after administration of the oral dose, in the patient's stomach, the outer layer of levodopa and carbidopa, which have an immediate release formulation, has dissolved, leaving a bead containing carboxylic acid, but no levidopa or decarboxylase inhibitor. Impax contends that the layer of levidopa and a decarboxylase inhibitor on the tartaric acid bead are an insubstantial modification, and that the Actavis product performs the same function as the patented formulation in substantially the same way to achieve the same result. The Court need not reach the merits of this theory now. Actavis moved for summary judgment of no infringement, under the doctrine of equivalents, with regard to the Formulation Structure Claims, based on prosecution history estoppel; this Court has decided to deny the motion on these issues, and need not reach the details of a doctrine of equivalents infringement theory that Impax might advance at trial.

Thus, as to the Formulation Structure Claims, no claims that depend on proof of literal infringement survive this motion. Any Formulation Structure Claims that depend on infringement of the Formulation Structure Claims under the doctrine of equivalents survive this motion.

II. Infringement of claims requiring a particular PK profile

For purposes of this motion, the parties have grouped together method of use claims in the '246, '046, and '608 patents that require pharmacokinetic profiles with certain characteristics. In brief, one subset of claims contains claim limitations involving "maximum concentration" ("the 'maximum concentration' claims") while the other subset of claims contains

claim limitations with the term, "the levodopa blood plasma levels do not fluctuate more than 40% between 0.5 hours and six hours after administration" ("the '40% fluctuation' claims). Actavis moves for summary judgment of literal noninfringement on all such claims on the ground that its proposed product does not meet these limitations. Although, as already discussed, all method of use infringement claims can only be for indirect infringement, Actavis raises the direct infringement issue as a predicate for the indirect infringement claims.

As to both the maximum concentration claims and the 40% fluctuation claims, Impax argues that Actavis now asserts new arguments against infringement that should be barred as untimely because they were not disclosed in the disclosures of non-infringement contentions required by this district's Local Patent Rules. As to the 40% fluctuation claims, this Court agrees that Actavis now pursues a new argument that will be barred.

Local Patent Rules 3.2A(a) and 3.6(e) require a party accused of patent infringement to submit a disclosure stating "[t]he written basis for its Non-Infringement Contentions and responses," which Actavis did; its disclosure regarding the '246 patent is dated January 20, 2017, while its disclosure regarding the '046 patent is dated July 11, 2017. (Drummond 2nd Dec. Exs. 1, 2.) As to the 40% fluctuation limitation in the PK profile claims, the two disclosures are similar, and contain the subheading, "Plasma Concentration Profile – All Claims." (Drummond 2nd Dec. Ex. 1 at 8.) In this section, in summary, Actavis states that there is no evidence that its products "result in a levodopa plasma concentration" meeting the 40% fluctuation limitation. The next paragraph restates this point, and, as to both patents, that is all that is said on this topic.

Impax argues that the non-infringement contentions submitted by Actavis "gave no hint of the specific arguments it now makes." (Impax Opp. Br. 18.) As to the 40% fluctuation

limitation, this is correct. Actavis now moves for summary judgment with the argument that its products do not infringe the 40% fluctuation limitation when one calculates two different 40% ranges, instead of one. In its noninfringement contentions, Actavis gave no suggestion that the method of calculating the 40% fluctuation range was at issue, or that it would argue noninfringement based on how the range was computed. There is nothing to suggest that Actavis intended to point to a calculation method disclosed in the prosecution history.

In the instant motion, Actavis argues that, although the specifications of the patents at issue do not tell a skilled artisan how to calculate and test the 40% fluctuation limitation, the prosecution history gives guidance in two places, in which the applicants use a two-range calculation method as a test of infringement. Actavis contends:

> Particularly in the absence of a specific directive to select one or the other points to calculate the fluctuation range, a POSA would understand that administration of a formulation only meets this limitation if the LD plasma concentrations stay within the range of ±40% of the concentrations at both the 0.5-hour and 6-hour time points.

(Actavis Br. 20.) This Court agrees with Impax that the non-infringement contentions give no hint of this noninfringement theory. As such, use of this previously undisclosed noninfringement argument is barred. As to the 40% fluctuation claims, the motion for summary judgment will be denied.

Impax also raises this argument as to the motion for summary judgment on the "maximum concentration" claims. Here, however, this Court finds that the noninfringement contentions adequately disclose Actavis' present argument. As just discussed, in its noninfringement contentions, Actavis disclosed that it would argue that Impax has no evidence

that the Actavis products meet the claim limitations regarding the second concentration.[5] This is exactly the argument that Actavis has made to the Court in its present motion for summary judgment of noninfringement. This argument was previously disclosed in accordance with the Local Patent Rules.

A. the "maximum concentration" claims

Claim 21 of the '608 patent, and all of the asserted claims of the '246 and '046 patents require that the LD plasma concentration profile have certain characteristics. Among these is the requirement that the profile have "a second concentration at a second time" where "said second concentration is equal to the maximum concentration of said profile." Claim 21 of the '608 patent is representative:

> A controlled release oral solid formulation of levodopa having a median levodopa plasma or serum concentration profile comprising:
>
> a. a time of administration;
> b. a first concentration at a first time, that occurs within one hour of said time of administration;
> c. a second concentration at a second time, that occurs after said first time;
> d. a third concentration at a third time, that occurs at least four hours after said second time;
> wherein said second concentration is equal to the maximum concentration of said profile; said first concentration is equal to about fifty percent of said second concentration; said third concentration is equal to about fifty percent of said second concentration.

The asserted claims in the '246 and '046 patents use substantially similar, but not identical, language.

The parties have complicated their dispute over infringement of these claims by briefing

[5] Although the noninfringement contentions do not point specifically to the claim term, "maximum concentration," the Actavis contentions expressly point to the second concentration, which is the maximum concentration of the profile.

claim construction of the phrase, "maximum concentration." To cut to the chase, however, the briefs show no sign of any actual dispute over the meaning of the claim term, "maximum concentration." It is crystal clear that the parties have the same understanding of what a concentration is, and they agree that the maximum is the highest value. Despite the fact that there is no actual dispute over the meaning of "maximum concentration," the parties devote pages of their briefs to the subject.

Actavis argues that "maximum concentration" should have its ordinary meaning, the highest concentration. Impax agrees, stating: "The parties agree that the plain and ordinary meaning of the term is the highest concentration of levodopa in the plasma concentration profile." (Impax Opp. Br. 21.) Impax contends, however, that "Actavis goes awry in how it applies this construction." (Id. at 21-22.) Again, to cut to the chase, Impax then proposes an analytic procedure for determining the maximum concentration that may be expressed with these rules: 1) concentration data should be rounded to two decimal places of precision; 2) the maximum is selected from the rounded data; and 3) in the case of a tie between rounded data values, the maximum concentration is the first in time.

Impax's contention that this special analytic procedure should be followed is unpersuasive. First, it has no basis in patent law. Impax states that this is not a matter of claim construction, but provides no legal theory to justify its contention that this special procedure – which transforms the raw data before profile analysis – should be followed to determine infringement. Second, the only mooring for this argument in the facts appears to be the observation that, when Actavis reported clinical data on the proposed generic to the FDA, some data was reported with four decimal places of precision, but some summary statistics (such as

mean and median) were reported as rounded to two decimal places of precision. Impax has failed to explain why this observation has any significance, let alone why some format characteristics of an FDA submission have any impact on the infringement analysis. The FDA submissions of the accused infringer are not even statements by the patentee, so what is the relevance here?

Impax attempts to turn this into a dispute between experts that precludes a grant of summary judgment, but this has no merit. First, as just discussed, Impax has no coherent theory here but, even if it did, it cites three expert statements that contain no relevant evidence. The cited paragraph (72) of the Jusko rebuttal expert report says nothing about its proposed "maximum concentration" special analytic procedure. (Impax Opp. Ex. 21.) In the cited deposition testimony of expert Dr. Amiji, Dr. Amiji states his expert opinion that there is no statistically significant difference between mean concentration values of .45 and .46, given a standard deviation of .2. (Impax Opp. Ex. 23 at 189:1-191:12.) The question of whether concentration values differ to a statistically significant degree has no relevance to the issues at hand. Nor does the snippet of deposition testimony from expert Dr. Jusko say anything relevant. (Impax Opp. Ex. 24 at 155:25-156:22.) Thus, even if Impax had a viable legal theory to support its proposed special analytic procedure, it has cited no expert statements which support the use of this procedure.

Impax has failed to persuade the Court to round the plasma concentration data to two decimal places when finding the maximum concentration. There appears to be no dispute that, if one does not round the data to two decimal places of precision, the Actavis clinical study data does not show infringement of the "maximum concentration" limitations. Actavis moved for

summary judgment of noninfringement on the ground that Impax has no evidence that the proposed product infringes. Impax, in opposition, failed to point to evidence which raised any genuine factual dispute about this question. Impax has failed to defeat the motion for summary judgment of noninfringement on the method of use claims that contain "maximum concentration" limitations. Impax has no evidence of direct literal infringement of these claims and, in the absence of evidence of direct infringement, there can be no proof of indirect infringement. As to the issue of literal infringement, in regard to the counts based on the method of use claims that contain "maximum concentration" limitations, the motion for summary judgment will be granted. See Intellectual Ventures I LLC v. Motorola Mobility LLC, 870 F.3d 1320, 1331 (Fed. Cir. 2017) ("a finding of direct infringement is predicate to any finding of indirect infringement").

Actavis also moves for summary judgment of noninfringement of the "maximum concentration" claims under the doctrine of equivalents. The parties each give very brief treatment to this dispute. Actavis says Impax has no evidence of infringement, but admits that Impax's expert contends that there is infringement under the doctrine of equivalents. Indeed, Dr. Amiji's supplemental report asserts infringement under the doctrine of equivalents, noting that when one compares the plasma concentration profiles for the branded product and the proposed generic, they are nearly identical. (Amiji Supp. Rpt., Impax Opp. Ex. 19 at ¶ 63.) Actavis argues that Amiji's analysis is deficient. While it may indeed be true that Amiji's analysis is ultimately not credited by the finder of fact, at this juncture, his expert opinion regarding infringement of "maximum concentration" claims under the doctrine of equivalents raises a material factual dispute sufficient to defeat the motion for summary judgment of

noninfringement, as to this narrow issue of doctrine of equivalents infringement only.

Actavis moves for summary judgment as to all indirect infringement claims based on the '246 and '046 patents, on the ground that Impax cannot prove inducement or contributory infringement. As to inducement, Actavis contends that Impax has no evidence that Actavis possessed the requisite specific intent to induce infringement. Specifically, Actavis argues: 1) the proposed label states that the product may be taken with or without food; and 2) the ACT-15004 study results shows that administration of the Actavis product under fed conditions does not meet the PK profile limitations of any claims. Therefore, Actavis contends, the proposed product label does not encourage infringement.

"To prove inducement, the patentee must show direct infringement, and that the alleged infringer knowingly induced infringement and possessed specific intent to encourage another's infringement." i4i Ltd. P'ship v. Microsoft Corp., 598 F.3d 831, 851 (Fed. Cir. 2010) (citation omitted).

Actavis argues that this case is identical to the facts of Shire LLC v. Amneal Pharm., LLC, Civil Action No. 11-3781 (SRC), 2014 U.S. Dist. LEXIS 85369, at *15 (D.N.J. June 23, 2014). As Impax argues, however, the key difference in Shire is that the patent claims at issue in Shire contained specific limitations regarding administration in a fed state:

> 2. A method of treating an adult subject having attention deficit hyperactivity disorder, said method comprising orally administering to said subject a pharmaceutically effective amount of L-lysine-d-amphetamine or a pharmaceutically acceptable salt thereof with intake of food by said subject.

U.S. Patent No. 7,659,254. In Shire, the proposed label stated that the products may be taken with or without food. This Court held:

> The problem is that the statement that the medication may be taken with or

> without food cannot be reasonably understood to be an instruction to engage in an infringing use. As Defendants contend, it is indifferent to which option is selected. At most, it may be understood to permit an infringing use, but permission is different from encouragement. Plaintiffs point to the statements of their expert, Dr. McGough, but none of his conclusory assertions get around the simple fact that the proposed label does not contain any instruction to take the medication with food. Plaintiffs have failed to raise a material factual dispute over whether the proposed label encourages infringement of method claims requiring administration with food.

Shire, 2014 U.S. Dist. LEXIS 85369 at *16. Actavis contends that the instant case has the same facts and should lead to the same result.

Impax, in opposition, distinguishes Shire on the ground that the claims at issue in the present case contain no limitations regarding being fed or fasted. In addition, Impax points to various pieces of evidence tending to prove that Actavis designed its proposed product so as to duplicate a key plasma concentration curve in the patent.

This Court concludes that the facts of Shire are not analogous: the patented method included administration with food, and this Court concluded that the label did not encourage the performance of a method step. In the present case, the patented method has no requirements about food. What the proposed label here says about food has no link to the patented method. In this case, what the label says about food or fasting has no relevance to the inquiry into specific intent to induce infringement.

Furthermore, the general argument that Actavis makes here is one that the Federal Circuit has rejected. Actavis has pointed to the evidence that not all patients will engage in an infringing use, and that there is a substantial noninfringing use. The Federal Circuit focuses the inquiry into specific intent to induce infringement on what the label instructs, rather than on whether some proportion of uses will or will not end up infringing.

The Federal Circuit's decision in AstraZeneca is more apposite:

Apotex, joined by two amici, mounts multiple challenges to the district court's finding that Apotex had the necessary specific intent to induce infringement. Apotex first contends that the district court inferred specific intent to induce infringement from Apotex's planned distribution of the generic drug. Apotex argues that drawing such an inference is improper where the product in question has substantial non-infringing uses. AstraZeneca responds that the district court based its specific intent finding not on an improper inference but rather on the circumstances surrounding Apotex's decision to proceed with its planned distribution of the generic drug and the affirmative evidence of intent provided by the proposed label.

This court agrees with AstraZeneca. Apotex is correct that "where a product has substantial noninfringing uses, intent to induce infringement cannot be inferred even when the [alleged inducer] has actual knowledge that some users of its product may be infringing the patent." *Warner-Lambert Co. v. Apotex Corp*., 316 F.3d 1348, 1365 (Fed. Cir. 2003). However, "liability for active inducement may be found 'where evidence goes beyond a product's characteristics or the knowledge that it may be put to infringing uses, and shows statements or actions directed to promoting infringement.'" *Ricoh Co. v. Quanta Computer Inc.*, 550 F.3d 1325, 1341 (Fed. Cir. 2008) (quoting *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.* ("*Grokster*"), 545 U.S. 913, 935, 125 S. Ct. 2764, 162 L. Ed. 2d 781 (2005)). As the Supreme Court explained in *Grokster* in the context of infringement under the copyright laws, "[e]vidence of active steps . . . taken to encourage direct infringement, such as advertising an infringing use or instructing how to engage in an infringing use, show an affirmative intent that the product be used to infringe." 545 U.S. at 936 (internal quotation marks and citations omitted).

The district court correctly concluded that such evidence exists here. As an initial matter, the district court suggested that there was insufficient evidence to establish that any noninfringing use of the generic drug was substantial, calling into question the applicability of the "substantial non-infringing use" doctrine in this case. Opinion at 605 n.25. Be that as it may, the district court found that Apotex had the requisite specific intent to induce infringement because Apotex included instructions in its proposed label that will cause at least some users to infringe the asserted method claims. *Id.* at 605. The district court also found that, despite being aware of the infringement problem presented by the proposed label, Apotex nonetheless proceeded with its plans to distribute its generic drug product. Supplemental Opinion at 618. This conduct, not merely the planned distribution of the generic drug, formed the basis of the district court's specific intent finding. *See id.* at 618-19. To the extent that Apotex contends that such circumstantial evidence cannot support a finding of specific intent, this court has explicitly

> stated otherwise. *Water Techs. Corp. v. Calco, Ltd.*, 850 F.2d 660, 668 (Fed. Cir. 1988) ("While proof of intent is necessary, direct evidence is not required; rather, circumstantial evidence may suffice." (citation omitted)).

AstraZeneca LP v. Apotex, Inc., 633 F.3d 1042, 1059-60 (Fed. Cir. 2010).

A more recent relevant case is Eli Lilly & Co. v. Teva Parenteral Meds., Inc., 845 F.3d 1357, 1368 (Fed. Cir. 2017). In Lilly, considering whether the generic product's proposed label taught an infringing use, the Court rejected the argument that not all users would infringe: "we have not required evidence regarding the general prevalence of the induced activity." The lesson of Lilly is that the key question is whether the label teaches performance of an infringing use, and that evidence of the prevalence of that infringing use is not part of that analysis.

Furthermore, the Federal Circuit has made clear that the existence of substantial noninfringing uses does not preclude a finding of inducement of infringement:

> Watson and Sandoz contend that, because Multaq® has substantial noninfringing uses not forbidden by the proposed labels, the district court could not permissibly find intent to encourage an infringing use. But there is no legal or logical basis for the suggested limitation on inducement. Section 271(b), on inducement, does not contain the "substantial noninfringing use" restriction of section 271(c), on contributory infringement. And the core holding of *Grokster*, a copyright decision that drew expressly on patent and other inducement law, is precisely that a person can be liable for inducing an infringing use of a product even if the product has substantial noninfringing uses (like the peer-to-peer software product at issue there, which was capable of infringing and non-infringing uses). There is no basis for a different inducement rule for drug labels.
>
> The content of the label in this case permits the inference of specific intent to encourage the infringing use. As noted above, inducement law permits the required factual inferences about intended effects to rest on circumstantial evidence in appropriate circumstances. Moreover, in *AstraZeneca v. Apotex*, the court upheld an inducement finding without the kind of explicit limiting commands that Watson and Sandoz suggest a label must contain. 633 F.3d at 1058-60. In *Eli Lilly & Co. v. Teva Parenteral Medicines, Inc*., the court stated that "[d]epending on the clarity of the [drug label's] instructions, the decision to continue seeking FDA approval of those instructions may be sufficient evidence of specific intent to induce infringement." 845 F.3d 1357, 1368-69 (Fed. Cir.

> 2017) (internal citations omitted). Unlike in *Takeda*, the inference in the present case is based on interpreting the label's express statement of indications of use and the internally referred-to elaboration of those indications. *See* 785 F.3d at 625. And this case is not like *Vita-Mix Corp v. Basic Holding, Inc.*, in which the defendant, in its (non-pharmaceutical) product instructions, encouraged a non-infringing use in a way that showed an intent to discourage infringement. 581 F.3d 1317, 1328-29 (Fed. Cir. 2009). The evidence in this case supports the finding of intentional encouragement of infringing use and, therefore, of inducement.

Sanofi v. Watson Labs. Inc., 875 F.3d 636, 646 (Fed. Cir. 2017) (citations omitted).

The instant case is similar to AstraZeneca: a reasonable finder of fact could conclude that the product label instructs physicians to perform steps that would produce infringement of every claim limitation, for the PK profile claims. As in AstraZeneca, Actavis has "included instructions in its proposed label that will cause at least some users to infringe the asserted method claims." A reasonable finder of fact could also find that the label evidence, together with other circumstantial evidence, is sufficient for a finding that Actavis had the specific intent to induce infringement of the PK profile method claims. The question of specific intent to induce infringement is a matter for the finder of fact at trial.

The Third Circuit has held: "The issue of intent is particularly inappropriate for resolution by summary judgment because evaluating state of mind often requires the drawing of inferences from the conduct of parties about which reasonable persons might differ." Justofin v. Metro. Life Ins. Co., 372 F.3d 517, 524 (3d Cir. 2004). This is certainly true of the argument that Actavis has made, which does require the drawing of inferences from the conduct of parties about which reasonable persons might differ.

The question of specific intent to induce infringement is a question of fact for the finder of fact. This is not a case in which the evidence of intent is so one-sided as to preclude any

material factual dispute. As to the question of inducement of infringement of the PK profile claims, the motion for summary judgment will be denied so that the matter may be submitted to a finder of fact.

Actavis also moves for summary judgment as to all contributory infringement claims based on the '246 and '046 patents, again, on the ground of substantial noninfringing uses. In contrast to the issue of induced infringement, here there is relevant language in the authorizing statute:

> (c) Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, *and not a staple article or commodity of commerce suitable for substantial noninfringing use*, shall be liable as a contributory infringer.

35 U.S.C. § 271 (italics added). As just discussed, there is a material factual dispute over whether the Actavis product is suitable for substantial noninfringing use, and this dispute must be resolved by the finder of fact at trial. As to the question of contributory infringement of the PK profile claims, the motion for summary judgment will be denied so that the matter may be submitted to a finder of fact.

For these reasons,

IT IS on this 8th day of March, 2018

ORDERED that Actavis' motion for summary judgment of noninfringement (Docket Entry No. 142), pursuant to Federal Rule of Civil Procedure 56), is **GRANTED** in part and **DENIED** in part; and it is further

ORDERED that, as to:

- all claims of infringement of claim 21 of the ’608 patent;
- all claims of literal infringement of claims 1, 2, 3, and 5 of the ’283 patent;
- all claims of literal infringement of claims 5, 8, 10, 13, 17, 18, and 19 of the ’608 patent;
- the issues of direct, literal infringement of claims 1, 9, 14, 17, 19, 21, 25, 26, 37, 40, 42, 44, 48, 49, 51, 53 of the ’246 patent; and
- the issues of direct, literal infringement of claims 7, 12, 14, 16, 18, 20, 21, 30, 31 of the ’046 patent

the motion for summary judgment is granted, and Judgment of noninfringement on these claims or issues is hereby entered in Defendant’s favor; and it is further

ORDERED that, as to all remaining issues, the motion for summary judgment is **DENIED**; and it is further

ORDERED that Actavis is barred from using its two-range calculation theory as a defense against infringement of the claims with a “40% fluctuation” limitation.

s/Stanley R. Chesler
STANLEY R. CHESLER, U.S.D.J.